Actions and Reports with a Due Date Specified by the Medical Device User Fee and Modernization Act of 2002

November 14, 2002

Date Due (Time beyond Effective Date)	By	Requirement	Citation (to FD&C Act, where possible)
October 1, 2002 — Medical device premarket submissions made on or after this date are subject to fees.			*§ 738(a)(1)(A).*
October 26, 2002 — MDUFMA signed by President, becomes law. This is the effective date of most provisions of the act.			
December 25, 2002 (60 days)	FDA	FDA must establish an Office (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(A)
March 31, 2003	GAO	GAO must submit a report determining the amount obligated during FY 2002 for medical device compliance activities.	§ 704(g)(10)(B)
April 24, 2003 (180 days)	FDA	Publish criteria for the accreditation of third-parties to conduct inspections of class II and class III device manufacturers.	§ 704(g)(2)
April 24, 2003 (180 days)	NIH	NIH must submit to Congress a report describing research on breast implannts being conducted or supported by NIH.	MDUFMA Sec. 214(a)
April 26, 2003 (Six months)	FDA	FDA must identify the types of reprocessed single-use devices for which 510(k)s will be required in the future, and must publish a list of those devices in the *Federal Register*. 510(k)s for these devices must include "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of time the device is reprocessed as intended" by the person who submits the 510(k). § 510(o)(1)(A). Publication of this list also triggers the timeframe for submission of validation data for devices on this list that *already have* a 510(k); see below at January 26, 2004.	§ 510(o)(1)(A)
April 26, 2003 (Six months)	FDA	FDA is to review the types of *critical* reprocessed single-use devices that are currently exempt from 510(k), and determine which of these exemptions is to be terminated. FDA must publish a *Federal Register* notice listing these devices. 510(k)s submitted for these devices must include validation data, and must be submitted within 15 months of publication of the list.	§ 510(o)(2)
April 26, 2003 (Six months)	FDA	FDA must modify MedWatch forms to facilitate reporting of information relating to reprocessed single-use devices.	MDUFMA Sec. 303
July 1, 2003	GAO	*If* appropriations for FY 2003 are below a certain amount, GAO must report to Congress concerning "whether and to what extent [FDA] is meeting the performance goals identified for [FY 2003]" and whether FDA will meet future performance goals.	§ 738(g)(1)(A)(i)(II)
August 2, 2003	FDA	Fees for FY 2004 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year.	§ 738(c)(5)
August 2, 2003 (270 days)	FDA	FDA must issue guidance on information necessary to assure the safety and effectiveness of pediatric devices, and on protections for children in clinical trials of pediatric devices.	MDUFMA Sec. 213

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October 1, 2003 — Reduced 510(k) fee for small business goes into effect. [Note: Requires technical amendment; necessary restrictive language was omitted from the act.]			
October 26, 2003 (One year)	FDA	FDA must accredit third-parties to conduct establishment inspections; an eligible establishment would then be permitted to select any accredited person to conduct an inspection in lieu of an FDA inspection.	§ 704(g)(1)
October 26, 2003 (One year)	FDA	FDA must report to Congress on the "timeliness and effectiveness" of device reviews by centers *other than CDRH*. The report is to include recommendations on whether responsibility for regulating such devices should be reassigned within FDA.	MDUFMA Sec. 205
October 26, 2003 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
November 30, 2003	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (during FY 2003). This report is due no later than 60 days after the end of each fiscal year.	MDUFMA Sec. 103
January 26, 2004 (15 months, at most) — Holders of 510(k)s for reprocessed devices included on the list published by FDA pursuant to § 510(o)(1)(A) (see entry at April 26, 2003) must submit validation data to FDA within nine months of publication of the list. § 510(o)(1)(B).			
January 26, 2004 (15 months) — Requirement for labeling of reprocessed single-use devices becomes effective. § 502(v)(2).			
April 26, 2004 (18 months, at most) — Expiration of limit on number of persons who can be accredited to conduct inspections. In the first year following publication of accreditation criteria (see entry at 180 days), FDA may accredit no more than 15 persons. § 704(g)(2).			
April 26, 2004 (18 months)	FDA	FDA is to review the types of *semi-critical* reprocessed single-use devices that are currently exempt from 510(k), and determine which of these exemptions is to be terminated. FDA must publish a *Federal Register* notice listing these devices. 510(k)s submitted for these devices must include validation data, and must be submitted within 15 months of publication of the list.	§ 510(o)(2)
April 26, 2004 (18 months) — Requirement for a device to conspicuously bear the name of its manufacturer becomes effective. § 502(u).			
January 31, 2004	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2003). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103
July 1, 2004	GAO	*If* appropriations for FY 2004 are below a certain level, GAO must report to Congress concerning "whether and to what extent [FDA] is meeting the performance goals identified for [FY 2004]" and whether FDA will meet future performance goals.	§ 738(g)(1)(A)(ii)(II)
August 2, 2004	FDA	Fees for FY 2005 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year.	§ 738(c)(5)

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October 1, 2004 — Authority for third-party establishment inspections may be suspended for FY 2005 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2004 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
November 30, 2004	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (through FY 2004). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec. 103
January 31, 2005	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2004). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103
July 1, 2005	GAO	*If* total appropriations for FY 2003 - FY 2005 are below a certain level, GAO must report to Congress concerning "whether and to what extent [FDA] is meeting the performance goals identified for [FY 2005], and whether FDA will be able to meet all performance goals identified for fiscal year 2006."	§ 738(g)(1)(B)(ii)(II)
August 2, 2005	FDA	Fees for FY 2006 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year.	§ 738(c)(5)
October 1, 2005 — User fee authority may be suspended for FY 2006 if appropriations for FY 2003 through FY 2006 are less than an amount specified by the act. § 738(g)(1)(C).			
October 1, 2005 — Authority for third-party establishment inspections may be suspended for FY 2006 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2005 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
November 30, 2005	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (through FY 2005). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec. 103
January 31, 2006	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2005). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103
August 2, 2006	FDA	Fees for FY 2007 are to be set by FDA, and published in the *Federal Register*, 60 days before the start of the fiscal year.	§ 738(c)(5)

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October 1, 2006 — User fee authority may be suspended for FY 2007 if appropriations for FY 2007 are less than an amount specified by the act. § 738(g)(1)(D).			
October 1, 2006 — Authority for third-party establishment inspections may be suspended for FY 2007 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2006 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
October 26, 2006 (Four years)	GAO	GAO is to submit a report on the third-party inspection program, including a recommendation as to whether the program should be continued or terminated.	§ 704(g)(12)
October 26, 2006 (Four years)	FDA	FDA is to submit to congress a report concerning the adequacy of existing postmarket surveillance of 1) implanted devices used in children, and 2) devices used in pediatric populations. The report is to follow, and be based on, a study conducted by the Institute of Medicine under an agreement with FDA.	MDUFMA Sec. 212(c)
November 30, 2006	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (during FY 2006). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec. 103
January 10, 2007	FDA	FDA must submit to Congress a study of — • The effect of medical device user fees on our ability fo conduct postmarket surveillance. • The extent to which device companies comply with postmarket surveillance requirements. • Any improvements needed for adequate postmarket surveillance, and the amount of funds needed to do so. • Recommendations as to whether, and in what amount, user fees should be used for postmarket surveillance, if fees are extended beyond FY 2007.	MDUFMA Sec. 104(b)
January 10, 2007	FDA	FDA must submit to Congress a study on our experience with third-party reviews of 510(k)s.	§ 523(d).
January 31, 2007	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2006). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec. 103
[No date specified, but implicitly well in advance of October 1, 2007]	FDA	Public meeting to discuss FDA's proposed recommendations to Congress concerning goals and plans after FY 2007, and for reauthorization of the medical device user fee authority. FDA's proposed recommendations are to be published in the *Federal Register* prior to the public meeting.	MDUFMA Sec. 105(b)

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October 1, 2007 — User fee authority expires. MDUFMA Sec. 107.			
October 1, 2007 — Authority for third-party review of 510(k)s expires. § 523(c).			
October 1, 2007 — Authority for third-party establishment inspections may be suspended for FY 2008 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2007 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
November 30, 2007	FDA	Annual report to Congress concerning FDA's progress in achieving performance goals (through FY 2006). This report is due not later than 60 days after the end of each fiscal year.	MDUFMA Sec 103
January 31, 2008	FDA	Annual report to Congress concerning implementation of the authority for fees, and FDA's use of fees (collected during FY 2007). This report is due no later than 120 days after the end of each fiscal year.	MDUFMA Sec 103
January 31, 2008 — Section 103, and its requirement for annual reports to Congress, expires. MDUFMA Sec. 107.			
October 1, 2008 — Authority for third-party establishment inspections may be suspended for FY 2009 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2008 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
October 1, 2009 — Authority for third-party establishment inspections may be suspended for FY 2010 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2009 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
October 1, 2010 — Authority for third-party establishment inspections may be suspended for FY 2011 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2010 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
October 1, 2011 — Authority for third-party establishment inspections may be suspended for FY 2012 if appropriations are less than an amount specified by the act. § 704(g)(10)(A).			
October 26, 2011 (One year, and annually thereafter)	FDA	FDA must report to Congress on the activities and impact of the Office created (within the Office of the Commissioner) to coordinate and monitor the review of combination products.	§ 503(g)(4)(G)
October 1, 2012 — Third-party inspection authority expires. § 704(g)(11).			

Some MDUFMA provisions remain in effect after October 1, 2012; the only remaining provision that includes a specific action date is the requirement for an annual report to Congress on the Office created to coordinate and monitor the review of combination products.